510(k) Summary of Safety and Effectiveness

Non-Confidential Summary of Safety and Effectiveness

March 13, 2003

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ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055-9501

Tel (317) 335-3780
Fax (317) 335-9270

Official Contact: Paul Dryden - President
Proprietary or Trade Name: Fenestrated Infusion catheter
Common/Usual Name: Infusion catheter
Classification Name: Pump, infusion - accessory
Predicate Devices: I-Flow – Soaker Catheter – K994374
Merit Medical Systems – K991619

Device Description:

The infusion catheter is a small bore, 20 gauge, tube with holes at the tip to permit dispersion of the medication into the site. The overall catheter is 30" in length with various lengths of holes (fenestrations) of – 1.5", 3.0", and 5.0" with a standard Touhy Borst connector. The catheter has markings on the shaft to provide a reference guide for the clinician. May be available in a kit. Provided sterile.

Intended Use:

For use in a kit for nerve blocks or wound site pain management.

To provide continuous or intermittent delivery of local anesthetics or other medications to surgical wound sites and/or close proximity to nerves outside the epidural space. Routes of administration may be intraoperative or percutaneous.

As an accessory to Sorenson medical infusion pumps or as a standalone device, but not for use with gravity feed.

Single patient use only

Environment of Use: Hospital, Sub-acute Institutions

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General Technical Characteristics

Attribute	Proposed device
Indications for use	For use in a kit for nerve blocks or wound site pain management. To provide continuous or intermittent delivery of local anesthetics or other medications to surgical wound sites and/or close proximity to nerves outside the epidural space. Routes of administration may be intraoperative or percutaneous. As an accessory to Sorenson medical infusion pumps or as a standalone device, but not for use with gravity feed.
Intended for single use	Yes
Prescription	Yes
Intended population	Not applicable
Intended Environment of Use	Hospital, Sub-acute Institutions
Design	
20 gauge catheter of 30" length with holes at proximal end and standard Touhy Borst connector	Yes
Of various fenestration hole lengths	1.5", 3.0", 5.0"
Can be provided in a kit with 510(k) cleared devices	Yes
Materials	
Catheter – PEBAXX 6333 Clear	Yes
Ink –UV curable	Yes
Performance Standards	
None under Section 514	Yes

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed device is safe, effective, and substantially equivalent when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2003

Mr. Paul Dryden
President
ProMedics, Incorporated
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K024190
Trade/Device Name: Fenestrated Infusion Catheter
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: December 18, 2002
Received: December 19, 2002

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K024190** (To be assigned)

Device Name: Fenestrated Infusion Catheter

Intended Use: For use in a kit for nerve blocks or wound site pain management.

To provide continuous or intermittent delivery of local anesthetics or other medications to surgical wound sites and/or close proximity to nerves outside the epidural space. Routes of administration may be intraoperative or percutaneous.

As an accessory to Sorenson Medical infusion pumps or as a standalone device, but not for use with gravity feed.

Single patient use only.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024190

Prescription Use ✓ **or** **Over-the-counter use**
(Per CFR 801.109)